

REMARKS

Applicant cancelled claim 131, amended claims 7, 9, 33, 102, 106, 130, 132, and 147, and added new claims 156-174 to further define Applicant's claimed invention. The amendment to claim 102 is supported by claim 131 as originally filed. New claims 156-165 are supported at least by claims 7, 14, 15, 21, 22, 34, 38, and 40-42, respectively, as originally filed. New claims 166, 169, and 172 are supported by the specification at least on page 16, lines 4-6 and Figs. 4, 5, and 9. New claims 167, 168, 170, 171, 173, and 174 are supported at least by Figs. 4, 5, and 9. New claims 157, 158, 161-163, and 166-174 read on the invention of Group I, Species 1, Fig. 5. Applicant submits that the subject matter of new claims 156, 159, 160, 164, and 165 was not identified by the Examiner as being a separate, patentably distinct species and is therefore not subject to the Examiner's Restriction Requirement of November 30, 2001. Applicant submits that claims 156-174, dependent from one of independent claims 1, 102, and 147, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

A copy the Form PTO-1449 accompanying the Information Disclosure Statement (IDS) dated July 24, 2003 was returned with the Office Action without the Examiner's initials in the left-hand column. Applicant respectfully requests the Examiner to indicate that the entry on the Form PTO-1449 was considered by marking the appropriate column under the heading "Examiner Initial" and return a copy of the Form PTO-1449 to the Applicant with the next action.

In the Office Action, the Examiner objected to the specification under 37 C.F.R. § 1.75(d)(1) as failing to provide antecedent basis for the claimed subject matter. In particular, the Examiner contends that there is no antecedent basis in the specification for the phrases "facing side walls" and "inner surface facing each other." Applicant respectfully traverses the Examiner's objection. Antecedent support for the phrase "facing side walls" is found in the specification on page 11, line 9. Applicant amended the specification on page 11 to recite that the "interior and exterior facing side walls have an inner surface facing each other." Applicant submits that the objection to the specification under 37 C.F.R. § 1.75(d)(1) has been overcome.

The Examiner objected to the drawings under 37 C.F.R. § 1.83(a) for not showing every feature of the claimed invention. In particular, the Examiner contends that the features "facing side walls," "inner surfaces facing each other," "hollow interior," and "first distance greater than the third" are not shown. Applicant respectfully traverses the Examiner's objection relative to the feature of "facing side walls." Fig. 9A (previously Fig. 9) shows an interior facing side wall 112 and an exterior facing side wall 114. (See, e.g., Specification, page 16, lines 15-17). For the other features noted by the Examiner, Applicant is submitting concurrently herewith a proposed drawing correction with new Figs. 6B and 9B. Fig. 6B is a cross section of Fig. 5 showing the side walls having an inner surface facing each other. Fig. 6B also shows the hollow interior of implant 100. Fig. 9B shows an implant where the first distance C is greater than the third distance A.

New Fig. 6B is supported by the language of claim 35 as originally filed, page 16, line 20 of the specification, and Fig. 5. New Fig. 9B is supported by the language of claim 2 as originally filed and page 17, lines 16-19 of the specification. No new matter has been added.

The Examiner objected to the amendment to the specification filed September 11, 2002 under 35 U.S.C. § 132 as introducing new matter. Applicant respectfully traverses the objection. Applicant addressed this rejection in Applicant's reply of July 24, 2003 and repeats it here for the Examiner's convenience. The new paragraph added to the specification on page 17, after line 6 is supported at least by claim 39 as originally filed, which states that the opposed portions are "in moveable relationship to each other to allow for relative motion of the adjacent vertebral bodies after said implant is installed." Applicant respectfully brings to the Examiner attention that according to MPEP § 2163(I)(B), "[t]he claims as filed in the original specification are part of the disclosure...." (MPEP § 2163(I)(B), page 2100-157, col. 2 (August 2001); see also, MPEP § 608.01(I) "Original Claims," page 600-69, col. 2 (August 2001)).

The Examiner rejected claims 39 and 136 under 35 U.S.C. § 112, first paragraph, as failing to comply with the enablement requirement. Applicant respectfully

traverses the rejection and submits that the rejection was improperly made. The MPEP directs that the language of any enablement rejection "should focus on those factors, reasons, and evidence that lead the examiner to conclude that the specification fails to teach how to make and use the claimed invention without undue experimentation, or that the scope of any enablement provided to one skilled in the art is not commensurate with the scope of protection sought by the claims. This can be done by making specific findings of fact, supported by the evidence, and then drawing conclusions based on these findings of fact." (MPEP § 2164.04, page 2100-183, col. 2 (February 2003)). Applicant respectfully submits that the Examiner's rejection does not conform to the MPEP guidelines quoted above.

Applicant further submits that the subject matter of claim 39 complies with the enablement requirement of 35 U.S.C. § 112, first paragraph. The Examiner's statement in the Office Action that the embodiments taught in the application do not have opposed portions which are moveable "to adjust angulation of adjacent vertebral bodies" is not applicable because this limitation is not in either of claims 39 or 136. (See Office Action, page 3, second paragraph). The concept of relative motion is discussed in Applicant's specification where it is disclosed that "[m]otion preserving implants maintain the spacing between the two adjacent vertebral bodies and allow for relative motion between the vertebrae." (See Specification, page 3, lines 1-5). In the reply of July 24, 2003, Applicant provided U.S. Patent No. 5,258,031 to Salib et al. in an Information Disclosure Statement as an example of an implant applying the general concept of permitting relative motion. Another example of an implant applying the general concept of permitting relative motion is taught in U.S. Patent No. 5,609,635 to Michelson ("Michelson '635"), which the Examiner cited in the present Office Action. (See, e.g., Michelson '635, Fig. 30). According to the MPEP, "[a] patent need not teach, and preferably omits, what is well known in the art." (MPEP § 2164.01 "Test of Enablement," page 2100-179, col. 1 (February 2003)(citing *In re Buchner*, 929 F.2d 660, 661 (Fed. Cir. 1991))). The concept of an implant having "opposed portions in

moveable relationship to each other to allow for relative motion of the adjacent vertebral bodies after the implant is installed is well known in the art. Accordingly, Applicant submits that the subject matter of claim 39 is fully enabled as would be recognized by one skilled in the pertinent art.

The Examiner's statement that the current application is "a 09/553000 which does not even support this limitation" is not understood. (See Office Action, page 3, second paragraph). Applicant assumes that the Examiner meant to refer to the present application, Serial No. 09/553,573. Applicant submits that the specification of the present application supports the subject matter of claims 39 and 136 for the reasons stated below with respect to the Examiner's rejection for failing to comply with the written description requirement under 35 U.S.C. § 112, first paragraph.

The Examiner rejected claims 1-34, 36-42, and 141-143 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement. Applicant respectfully traverses the Examiner's rejection. According to the MPEP, "[t]o satisfy the written description requirement, a patent specification must describe the claimed invention in sufficient detail that one skilled in the art can reasonably conclude that the inventor had possession of the claimed invention." (MPEP § 2163(I), page 2100-159, col. 1 (February 2003)). Applicant submits that the limitation "said hollow interior having a maximum dimension...greater than said maximum dimension of said opening" is fully supported in the specification. Independent claim 1 as originally filed claimed an implant having opposed portions adapted to contact and support the adjacent vertebral bodies. Claim 35 as originally filed further defined each of the opposed portions to have an interior surface, "said interior surfaces being spaced apart to define a hollow interior in communication with said openings." (Specification, claim 35 as originally filed). As stated above, "[t]he claims as filed in the original specification are part of the disclosure...." (MPEP § 2163(I)(B), page 2100-157, col. 2 (August 2001)). Accordingly, Applicant at least has support in the specification for an implant having a hollow interior which is defined in part by upper and lower surfaces that are spaced apart, facing one another, and in communication with the openings.

Further, each of the opposed portions have at least one opening therein and the opposed portions each have spaced-apart interior surfaces. It is inherent that the hollow interior has a maximum dimension between the inner surfaces of the interior and exterior facing side walls and in a plane perpendicular to the mid-longitudinal axis of the opening. As the opening is between the side walls, it has a maximum dimension in a plane perpendicular to its mid-longitudinal axis less than the maximum dimension of the hollow interior between the side walls in that same plane. Therefore, the maximum dimension of the hollow interior is greater than the maximum dimension of the opening. (See Exhibit A described below).

The Examiner contends that Figs. 5 and 6 show the implant to be solid between the openings. (Office Action, page 4, first paragraph). Applicant respectfully traverses the Examiner's contention. Fig. 6 shows a cross section of implant 100 taken through the thickness of the side wall between the top edge of side wall 112 and the leftmost column of openings 110. (See, e.g., Fig. 5). Fig. 6 shows the side wall of the implant with cross hatching to illustrate that the implant is made of an artificial material. (See specification, page 13, lines 8-18). Contrary to the Examiner's contention, Fig. 6 does not show that "the implant is solid between the openings" because as shown in Fig. 5, line 6--6 does not run between any of the openings.

Applicant submits that one skilled in the art would reasonably conclude that Applicant had possession of the claimed invention at the time the present application was filed. Accordingly, Applicant submits that the rejection of claims 1-34, 36-42, 101, and 141-143 for lack of written description has been overcome.

The Examiner rejected claims 1, 8, 9, 39, and 102-155 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicant regards as the invention. For the Examiner's rejection of claim 1, a marked-up copy of Fig. 6B showing the features relating to the claim recitations not understood by the Examiner is attached hereto as Exhibit A. Applicant notes that independent claim 1 is the only independent claim reciting the

dimensional limitation not understood by the Examiner. As stated in the specification, the interior facing side wall is the portion of the implant adapted to be placed toward another implant when the implant is inserted in pairs into the disc space. (See Specification, page 16, lines 17-19). The recitations of claim 1 relating to the maximum dimension of the hollow interior and the maximum dimension of the opening are shown and labeled for the Examiner's convenience in Exhibit A.

For the Examiner's rejection of claims 8, 9, 105, and 106, a marked-up copy of Fig. 9 showing the claim recitations not understood by the Examiner is attached hereto as Exhibit B. Applicant amended claim 9 to change the phrase "contour that goes" to "curve that extends" to further define Applicant's claimed invention. As shown in Exhibit B, a front view of implant 100 is drawn to illustrate "a line perpendicular to the mid-longitudinal axis of said implant in a plane dividing said implant into an upper and lower half." The line perpendicular to the mid-longitudinal axis is shown in dotted line in Fig. 9 of Exhibit B with the limitation "less than half of said leading end" along the perpendicular line being curved. The limitation "more than half of said leading end is a curve that extends from said exterior side wall toward the mid-longitudinal axis" is marked with small "x"s in Fig. 9 of Exhibit B.

For the Examiner's rejection of claims 39 and 136, Applicant submits that the use of the phrase "moveable relationship" relative to the orientation of the opposed portions is clear. Merriam Webster's Dictionary defines "moveable" as "capable of being moved." (See Merriam Webster's Collegiate Dictionary, 10th Ed., page 761 (1999), a copy of which is attached hereto). Merriam Webster's Dictionary defines "relationship" as "the state of being related or interrelated." (See Merriam Webster's Collegiate Dictionary, 10th Ed., page 987 (1999), a copy of which is attached hereto). Thus, opposed portions that are in "moveable relationship" to each other are capable of being moved relative to one another. Examples of implants with opposed portions in moveable relationship to one another are shown in U.S. Patent No. 5,258,031 to Salib et al. (cited in Applicant's IDS of July, 2003) and Michelson '635, cited by the Examiner in the present Office Action.

For the Examiner's rejection of claim 147, Applicant amended the phrase "interior side wall" on lines 25 and 28 to read "interior facing side wall," which has antecedent support on line 20 of the claim. In response to the Examiner's inquiry about the disc space, the specification defines the phrase "disc space" as "the space between adjacent vertebral bodies normally occupied by a spinal disc." (Specification, page 2, lines 22-23).

For the reasons set forth above, Applicant submits that the rejections of claims 1, 8, 9, 39, 102-155 under 35 U.S.C. § 112, second paragraph have been overcome.

The Examiner rejected claims 147-151 and 153 under 35 U.S.C. § 102(b) as being anticipated by French Publication No. 2,724,312 to Albert ("Albert"). Independent claim 147, as now amended, recites opposed portions having a vertebral body contacting surface adapted to be placed toward one of the adjacent vertebral bodies, "said vertebral body contacting portions being at least in part between said interior facing side wall and said exterior side wall." Albert teaches a superior plan and an inferior plan "open to allow their osseous filling." (Albert, page 4, paragraph 2 of the English translation; Fig. 2). Albert does not teach or suggest an artificial spinal implant having vertebral body contacting portions between an interior facing side wall and an exterior facing side wall as recited in Applicant's claimed invention.

Independent claim 147 also recites an artificial spinal implant having "a minimum length as measured from said leading end to said trailing end so that said leading end and said trailing end of said implant are adapted to rest upon portions of the apophyseal rim when implanted." The Examiner contends that the implant of Albert "is fully capable of being used with a spine to fulfilling the functional language of claim 147." (Office Action, page 6, lines 1-2). Applicant respectfully disagrees with the Examiner's contention. The MPEP requires that functional limitations "be evaluated and considered, just like any other limitation of the claim." (MPEP § 2173.05(g), page 2100-206, col. 2 (February 2003)).

Claim 147 recites that the implant has a "minimum length as measured from said leading end to said trailing end so that said leading end and said trailing end of said implant are adapted to rest upon portions of the apophyseal rim when implanted." In

Fig. 5, Albert shows a spacer 26 having ends 28, 29 that do not rest on portions of the apophyseal rim. Accordingly, Applicant submits that Albert fails to teach or suggest the functional limitation of claim 147.

The Examiner also rejected claims 102-155 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 5,397,364 to Kozak et al. ("Kozak"). Applicant assumes that the Examiner meant claims 102-140 and 144-155 because claims 141-143 depend from independent claim 1. Claim 102, as now amended, recites an artificial spinal implant having a width less than one-half the width of the adjacent vertebral bodies into which the implant is adapted to be inserted with opposed portions having "at least one opening therein, said openings being in communication with one another to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant." Kozak teaches a pair of solid lateral spacers 21 "having each a partial lens shape." (Kozak, col. 5, lines 50-51; Figs. 1 and 6). The lateral spacers 21 do not have at least one opening therein to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through the implant. Kozak does not teach or suggest an artificial spinal implant as recited in claim 102.

Independent claim 147 recites an artificial spinal implant having opposed portions with "at least one opening therein to permit for the growth of bone from adjacent vertebral body to adjacent vertebral body through said implant" and "a hollow interior in communication with said openings." Kozak teaches a pair of solid lateral spacers 21 "having each a partial lens shape." (Kozak, col. 5, lines 50-51; Figs. 1 and 6). The solid lateral spaces do not have at least one opening therein as recited in claim 147. Kozak does not teach or suggest an artificial spinal implant as recited in claim 147.

The Examiner rejected claim 152 under 35 U.S.C. § 103(a) as being unpatentable over Albert in view of U.S. Patent No. 5,609,635 to Michelson ("Michelson '635"). Applicant submits that the rejection over claim 152 is rendered moot at least because it depends from an allowable independent claim, or claims dependent therefrom.

The Examiner also rejected claims 1-34, 36-42, and 101-155 under 35 U.S.C. § 103(a) as being unpatentable over Michelson '635 in view of U.S. Patent No. 4,349,921 to Kuntz ("Kuntz"). Applicant respectfully traverses the rejection. Applicant respectfully submits that the combination of Michelson '635 and Kuntz is untenable and cannot be maintained for the reasons stated below.

A. The motivation used to support the combination of references is inapplicable.

Applicant respectfully submits that the motivation used to support the combination of Michelson '635 with Kuntz is inapplicable. The Examiner states in the Office Action that "[i]t would have been obvious to one having ordinary skill in the art to have used the teachings of Kuntz forming a spinal implant in two halves with any vertebrae prosthesis including that of Michelson because 'when a prosthesis for the lumber [sic] area is required, it has been found advantageous to make the prosthesis in two halves.'" (Office Action, paragraph bridging pages 7-8). Applicant respectfully submits that the Examiner's asserted motivation is inapplicable because Michelson '635 already accomplishes without modification what the Examiner states is the reason to combine the teachings of Michelson '635 with Kuntz, *i.e.*, "forming a spinal implant in two halves." Michelson '635 teaches the use of modular implants 400 that are inserted separately into the disc space. (Michelson, col. 10, lines 21-23; and Fig. 18). Accordingly, Applicant submits that one skilled in the art would not look to another reference for a teaching on forming a spinal implant in two halves when this feature is already taught by Michelson '635. (See MPEP § 2143.01, "the Prior Art Must Suggest the Desirability of the Claimed Invention," page 2100-125, col. 1 (February 2003)).

B. Kuntz teaches away from Michelson '635

Applicant further submits that the proposed combination of Michelson '635 with Kuntz is untenable because Kuntz teaches away from the implant of Michelson '635. Michelson teaches an implant having openings 115 that "provide for bone growth to

occur from the vertebrae through the openings 115 to the internal chamber 116.” (Michelson, col. 6, lines 59-61). Kuntz teaches a spinal spacer that preserves some flexibility of the spinal joint. (Abstract, lines 1-4). Kuntz does not disclose a spinal fusion implant and in fact explicitly teaches away from spinal fusion. According to Kuntz, implants that permit tissue ingrowth are disadvantageous and “dangerous” because of problems related to bacterial infection, susceptibility for repeated injury, difficulty in removal of the prosthesis, spinal cord compression, and dysphagia. (See Kuntz, col. 1, line 67 to col. 2, line 24).

Kuntz teaches that encapsulation of a solid implant is better than bone ingrowth into the surface of a porous implant because should the prosthesis become infected, the removal of an encapsulated implant would be “relatively simple.” (Kuntz, col. 6, lines 48-54). The teaching away from porous implants is an essential feature of the prosthesis taught by Kuntz and not “extraneous” as contended by the Examiner. Accordingly, Applicant submits that Kuntz teaches away from the disclosure of Michelson ‘635. (See MPEP § 2145(X)(D)(2), “References Cannot Be Combined Where Reference Teaches Away from Their Combination,” page 2100-157, col. 1 (February 2003)).

In response to Applicant’s last reply where Applicant argued that Kuntz taught away from Michelson ‘635, the Examiner contended that “the disadvantages of having a porous implant...is an extraneous teaching of Kuntz which is not relying upon in the rejection.” (Office Action, “Response to Arguments,” page 10). Applicant respectfully submits that the rejection is improper and must be withdrawn because, contrary to the Examiner’s contention, Kuntz’s explicit teaching away from porous implants is not “extraneous” and must be considered. According to the MPEP, “[a] prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention.” (MPEP § 2141.02, “Prior Art Must Be Considered In Its Entirety, Including Disclosures That Teach Away From The Claims,” page 2100-122, col. 2 (February 2003)).

C. The proposed combination still does not yield Applicant's claimed invention as recited in many of the claims.

Both independent claims 1 and 102 recite an implant having a third distance as measured from the junction of the leading end and the interior side wall to the plane perpendicular to and bisecting the length along the mid-longitudinal axis of the implant that is greater than a second distance as measured from the perpendicular plane to the junction of the leading end and the exterior side wall. Applicant submits that even if the combination of Michelson and Kuntz could be properly maintained, the combination would still fail to result in an implant having a leading end with a third distance that is greater than the first and second distances, respectively as recited in independent claim 102. (See, Michelson, Fig. 2, leading end 120; and Kuntz, Figs. 7-10). The combination also does not yield an implant where the first distance is greater than the second distance as recited in claim 2, where the first distance is less than the third distance as recited in claim 3, and where the third distance is substantially greater than the first distance as recited in claim 5.

As mentioned above, independent claim 147 recites an artificial spinal implant having "a minimum length as measured from said leading end to said trailing end so that said leading end and said trailing end of said implant are adapted to rest upon portions of the apophyseal rim when implanted." Neither Michelson '635 nor Kuntz teach or suggest, whether alone or in proper combination, an implant as recited in claim 147.

Applicant submits that independent claims 1, 102, and 147 are patentable and that dependent claims 2-34, 36-42, 101, and 103-176 dependent from one of independent claims 1, 102, and 147, or claims dependent therefrom, are patentable at least due to their dependency from an allowable independent claim.

In view of the foregoing remarks, it is respectfully submitted that the claims are patentable. Therefore, it is requested that the Examiner reconsider the outstanding rejections in view of the amendments to the claims and preceding comments. Issuance of a timely Notice of Allowance of the claims is earnestly solicited.

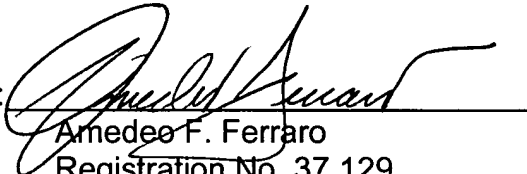
To the extent any extension of time under 37 C.F.R. § 1.136 is required to obtain entry of this reply, such extension is hereby respectfully requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17 which are not enclosed herewith, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge such fees to our Deposit Account No. 50-1066.

Respectfully submitted,

MARTIN & FERRARO, LLP

Dated: April 23, 2004

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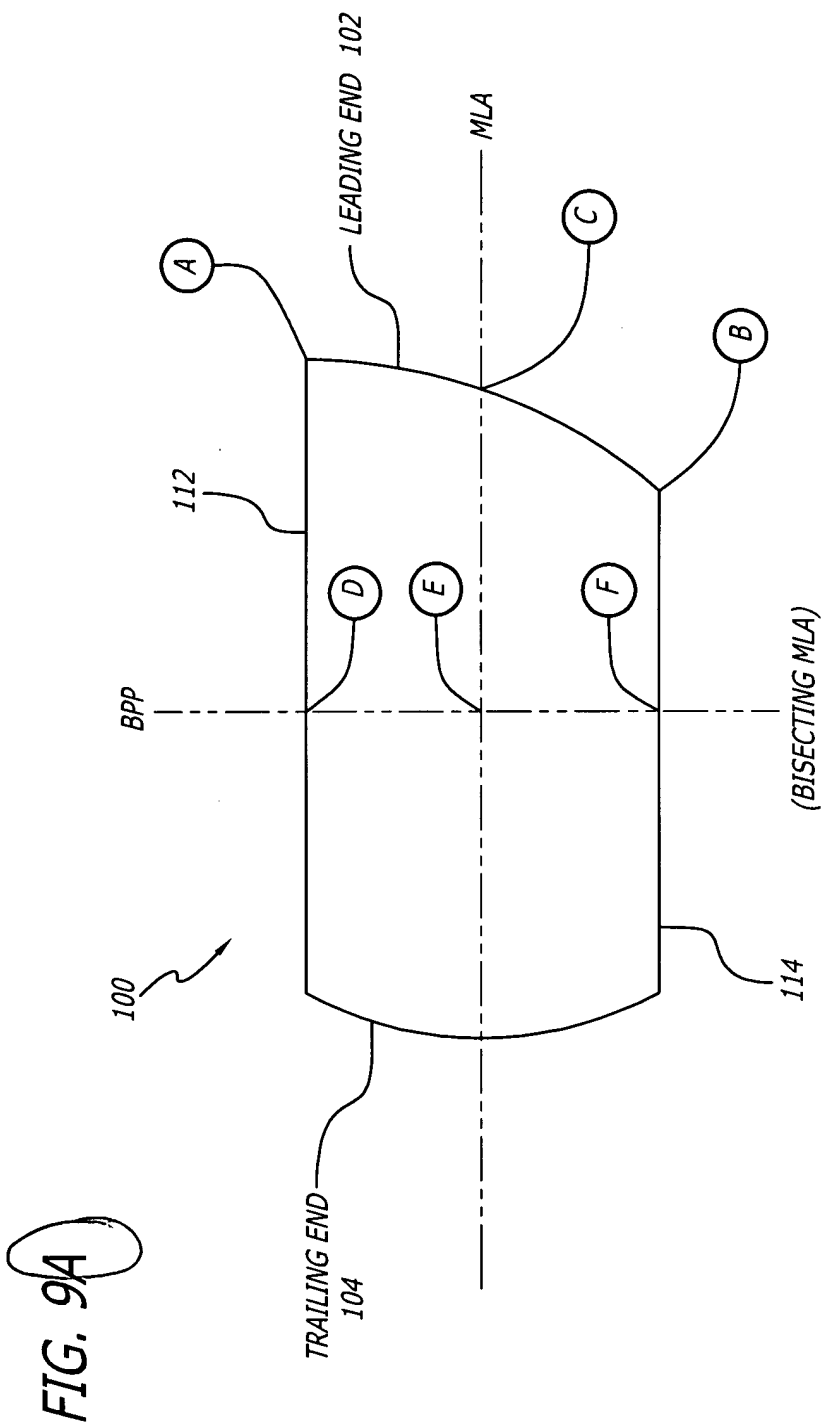
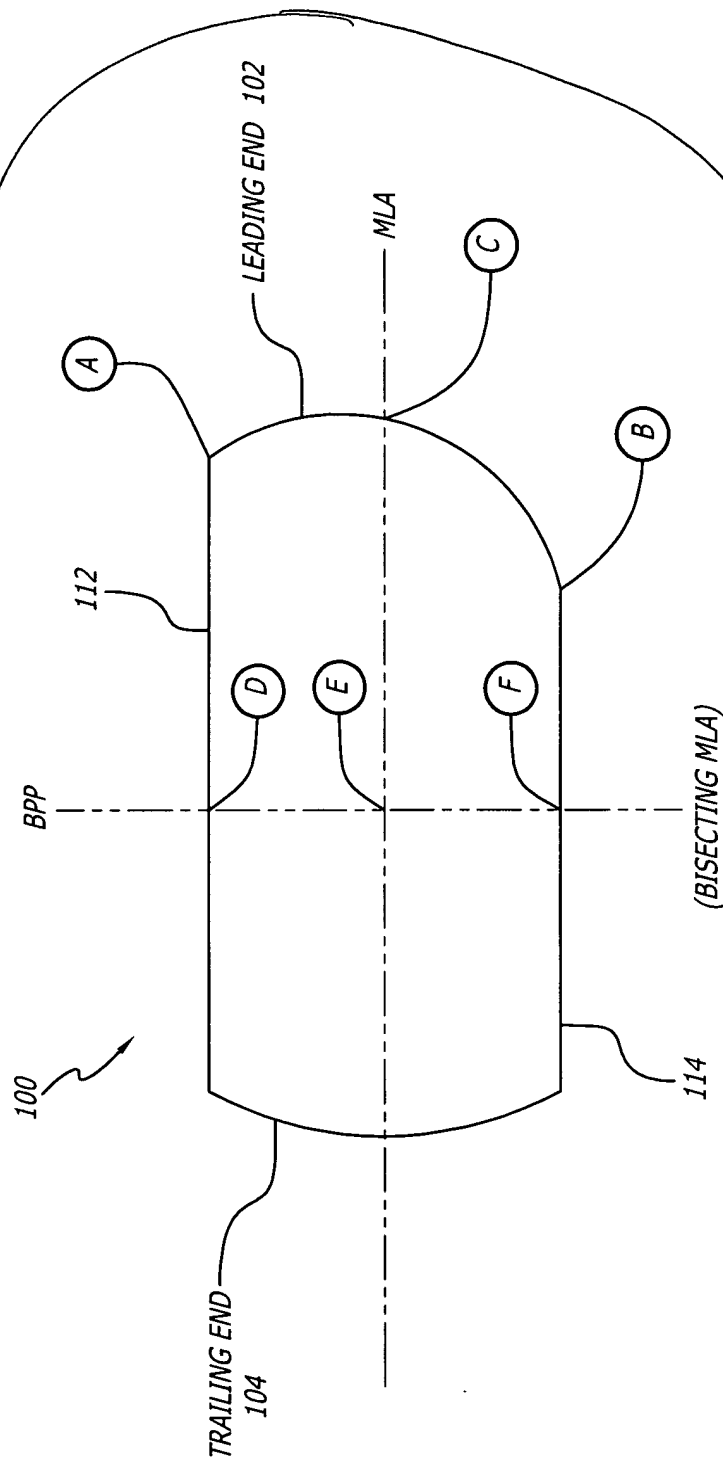




FIG. 9B



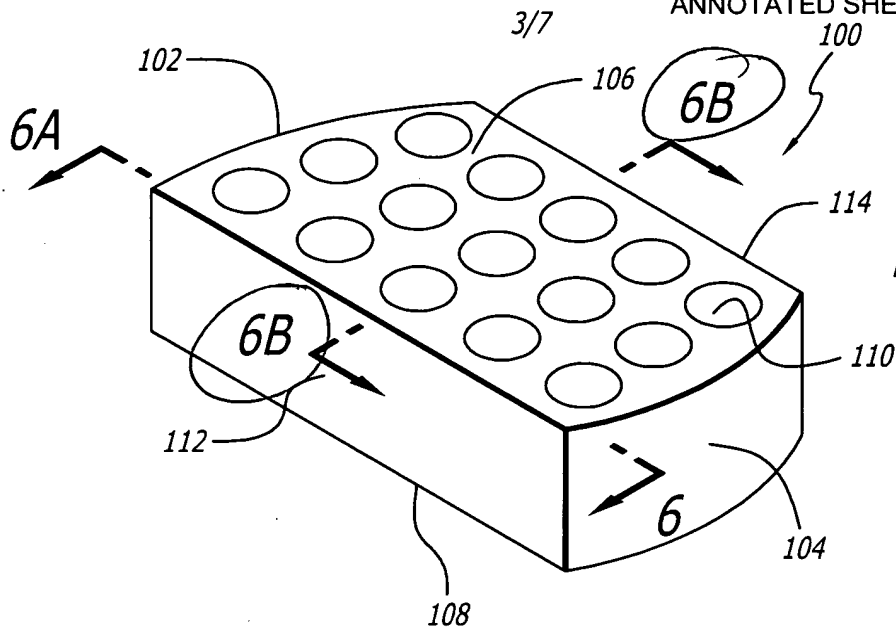


FIG. 5

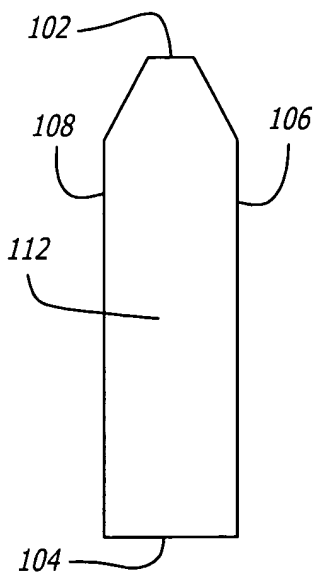


FIG. 5A

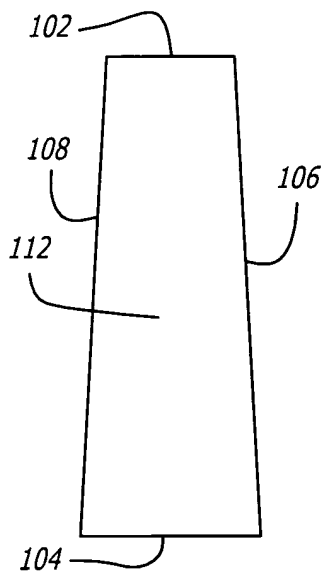


FIG. 5B

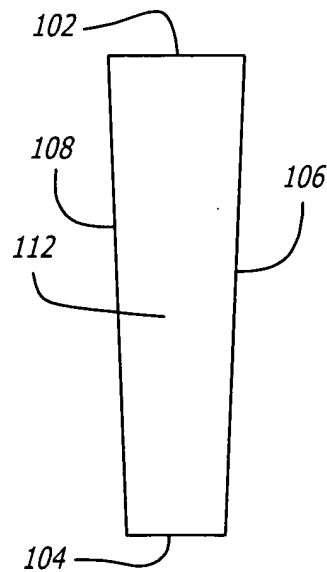


FIG. 5C

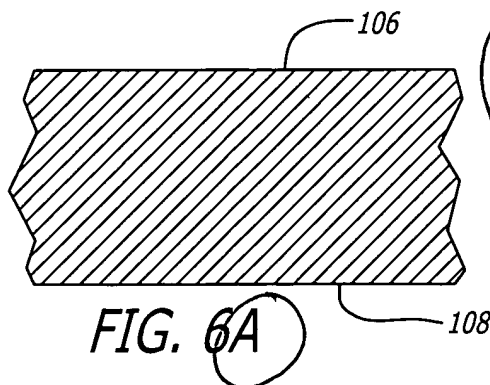


FIG. 6A

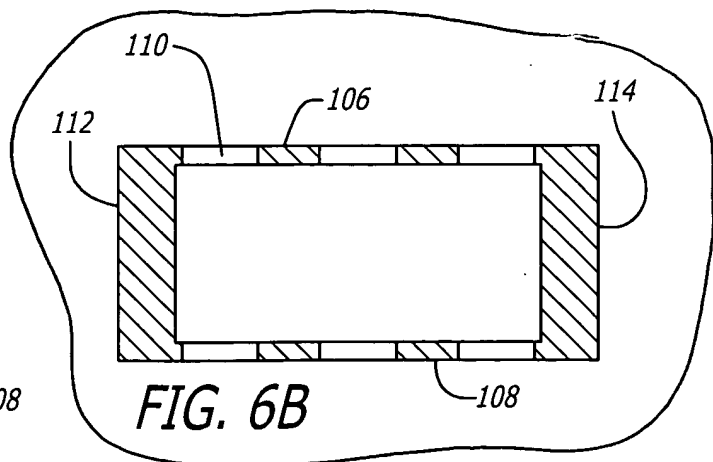


FIG. 6B